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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/747,996	12/29/2003	Yung-Ming Chen	50623.328	6554

7590 06/26/2007
Cameron Kerrigan
Squire, Sanders & Dempsey L.L.P.
One Maritime Plaza, Suite 300
San Francisco, CA 94111

EXAMINER

EDWARDS, LAURA ESTELLE

ART UNIT	PAPER NUMBER
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1734

MAIL DATE	DELIVERY MODE
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06/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/747,996

Applicant(s)

CHEN ET AL.

Examiner

Laura Edwards

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/29/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, drawn to an apparatus, classified in class 118, subclass 500.
- II. Claims 25-33, drawn to a method, classified in class 427, subclass 2.24.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used for a materially different process such as lubricating syringes.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark Lupkowski on 5/2/2007 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10, 12, 13, 21, 22, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by XP-000980708.

XP provides a system for coating an implantable medical device with a coating composition, comprising a reservoir (E) holding a coating composition; an applicator including a planar or flat sheet (C, D) including a coating surface and a porous region in fluid communication with the coating composition in the reservoir, wherein the porous region is capable of conveying the coating composition from the reservoir to the coating surface via wicking/capillary action; and a rotatable support element or mandrel (A) to support an implantable medical device in close proximity to or in contact with the coating surface of the applicator (see embods of Figs. 1 and 2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 5, 6, 8, 9, and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708.

The teachings of XP have been mentioned and while the planar sheet is used to coat the stent include foam, cloth (fibre/filament based material), etc., XP fails to suggest the pore characteristics of the foam or cloth. However, one of ordinary skill in the art would determine via routine experimentation, the appropriate pore characteristics including pore radius and degree of porosity, in accordance with the medical device being produced and the amount of coating material sought to be retained on the medical implant device.

With respect to claims 8, 9, 18, and 19, the XP system provides for a foam or sponge based porous sheet and even though a layered sponge or foamed sheet having different porosities, is not set forth, it would have been within the purview of one skilled in the art to

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provide a layered sponge or foamed sheet in order to control the wicking of the coating from the sheet or reservoir to the stent so as to provide a desired thickness of coating thereon.

With respect to the use of a pressure apparatus in the system, XP does not provide evidence to means for forcing the mandrel against the wall of the reservoir to force coating material out of the foam/sponge sheet onto the stent but one of ordinary skill in the art would expect to utilize a force to press the stent against the sheet since the sheet is porous and subject to deformation and subsequently degradation over a period of time.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Hijlkema et al (US 6,739,033).

The teachings of XP have been mentioned above but XP is silent concerning providing a temperature controller in communication with parts of the system so as to control the temperature of the coating material. However, it was known in the art, at the time the invention was made, to provide a temperature controller in communication with parts of a stent manufacturing/coating system in order to maintain a desired temperature of the coating on stent in order to prevent degradation of the coated stent product as evidenced by Hijlkema et al (col. 3, lines 11-24, col.6, lines 57 to col. 7, line 12). It would have been obvious to one of ordinary skill in the art to provide a temperature controller as taught by Hijlkema et al in communication with the XP system in order to maintain a desired temperature of the coating on stent to prevent degradation of the stent product.

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Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Frisch (US 4,906,423).

The teachings of XP have been mentioned but XP is silent concerning a porous applicator being inserted into the bore. However, it was known in the art to manufacturing a prosthetic device or stent, to provide for a porous mandrel to process the stent as evidenced by Frisch (col. 3, lines 60-65; col. 4, lines 23-37). It would have been obvious to one of ordinary skill in the art to provide a porous mandrel as taught by Frisch in the XP system as an interior means within the stent to allow for the transfer of coating material so as to coat inside the stent.

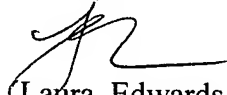
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Philip Tucker can be reached on (571) 272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Laura Edwards
Primary Examiner
Art Unit 1734

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June 22, 2007